



CONFIDENTIAL
REPORT

PEOPLE > SCIENCE > SOLUTIONS

Test Facility
6750 Wales Road
Northwood, OH 43619
419.666.9455

STUDY TITLE

Test of Sterility

TEST ARTICLE NAME

BI Lab testing for full cycle EO

TEST ARTICLE IDENTIFICATION

20190228/20190330/20190430

TEST ARTICLE PHYSICAL DESCRIPTION

See test specification.

TEST ARTICLE RECEIVED

June 4, 2019

SPONSOR

Jason Mercer
Kingpin Tattoo Supply
9715 International Court North
St. Petersburg, FL 33716

SUMMARY

This qualitative test was performed according to a NAMSA specification to determine if the biological indicators were sterile.

RESULTS

Bioindicator: *Bacillus atrophaeus* @10⁶

BI Lot Number: RA44

Article Tested	Number of Articles Tested	Type of Medium	Incubation Temperature (Degrees C)	Number of Days Incubated	Number of Positive Articles
Spore Strip	10	SCDB – 15 mL	30-35	7	0
Spore Strip Positive Control	1	SCDB – 15 mL	30-35	1	1

SCDB = Soybean Casein Digest Broth

Test Start Date: June 4, 2019


Test Termination Date: June 11, 2019

Control Start Date: June 4, 2019

Control Termination Date: June 5, 2019

METHOD

See the attached sterility test specification T0000732-05.

APPROVAL  for 11 June 2019

Lisa A. Schwalenberg, BS Date
Laboratory Supervisor, Sterility Assurance

Results apply only to the test article tested. Any extrapolation of these data to other articles is the sponsor's responsibility. This test was performed under all applicable GMP regulations and in compliance with the ISO 13485 standard, with the test method accredited to the ISO 17025 standard.



Test half the sample in SCDB and the other half in FTM.
 Test all samples received in SCDB.
 Test all samples received in FTM.

Incubate cultures at: 20-25°C for SCDB and 30-35°C for FTM 30-35°C 45°C 55-60°C
 28-32°C 20-25°C Other Steam or *Geobacillus stearothermophilus* bioindicators at 55-60°C, Ethylene oxide or *Bacillus atrophaeus* bioindicators at 30-35°C, or incubate per manufacturer's recommendations.

Incubation time: Minimum of 7 days 10 days 14 days 30 days
 Other

Background Info: USP AAMI: VD max EP Other: Not Applicable

B/F Testing performed on: Date: Not Applicable
 Lab Number (if test performed at NAMSA): Not Applicable

Reference(s): NAMSA Sterility test SOP series

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